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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

04/439888

Applicant(s)

Shi et al

Examiner

alab

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Pri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/14/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 2 + 4-7 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 2 + 4-7 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/02 has been entered.

The amendment of 11/14/02 amended claims 1, 2, 4, 5 and 6, added new claim 7, and canceled claim 3.

Claims examined on the merits are 1, 2 and 4-7 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 1, 2 and 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and claims dependent thereon are unclear by claim 1 not being a proper improvement claim. In a claim that requires an improvement in the preamble, the preamble must recite the known method to which the improvement applies. A method of improving an array of porous polymer pads as recited in the preamble of the claim is not a known method for modifying by an improvement. It is suggested that the

preamble of claim 1 be amended by replacing "improving" with -- producing --, and "improvement" with -- method --.

In step b of claim 1, "pads" should be -- pad --.

Claim 5 is unclear by requiring increasing the pore size in the
5 preamble but not requiring the steps recited to increase the pore size.
The claim should require freeze-drying as in claim 1 to increase pore size.

In line 2 of claim 5, there is no antecedent basis for "the porous polymer pads". Also, in line 1 of the claim, it is unclear as to what
10 forms the array. It is suggested that "the" be deleted, and -- of porous polymer pads -- be inserted after "array".

Claim Rejections - 35 USC § 103

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guschin et al or Khrapko et al (5,552,270) or Chetverin
15 et al (5,616,478) in view of Funk et al (5,973,014), and if necessary in further view of Ruchel (1978) or Ruchel (1975) or Blank et al for reasons set forth in the previous office action of 6/4/02.

The claims are drawn to a method of producing an array of porous polymer pads used in binding assays by providing an array of porous
20 polymer pads on the surface of a solid support, binding a specific substance to the porous polymer pads, freezing the array of pads on the support and drying the array of porous polymer pads on the support at reduced pressure to obtain porous polymer pads having increased pore size. Also claimed is an array of freeze-dried porous polymer pads on a
25 solid support produced by the method.

Guschin et al disclose drying an array of micromatrices of polyacrylamide gel pads on a support for use in immobilizing a compound such as DNA. See the abstract (page 203, left col); the paragraph bridging pages 202 and 204;; page 205, left col, first complete
5 paragraph; page 207, right col under "Microchip Fabrication"; and page 211, left col, under "CONCLUSION".

Khrapko et al (col 4, lines 1-15) and Chetverin et al (col 12, lines 55-62) disclose providing an array of porous polymer gel pads on the surface of a solid support and then drying the array of porous polymer
10 gel pads on the surface. Chetverin et al disclose the polymer gel being lyophilized or dried in vacuo (col 12, lines 58-59).

Funk et al disclose freeze drying swollen, non-porous, hydrophilic polymers to obtain porous, hydrophilic, highly swellable polymers having a desired pore size and pore distribution (col 2, line 58 to col 3, line
15 10), and which retain their original shape (col 3, lines 7-8). Monomers used to prepare the polymer can be amides of acids such as acrylic acid (col 3, lines 45-51). The amount of water in the swollen polymer being freeze dried can be used to control the pore size of the freeze dried polymer (col 3, lines 16-18).

20 Ruchel (1978), Ruchel (1975) and Blank et al disclose freeze drying polyacrylamide gels to obtain porous polyacrylamide polymers.

It would have been obvious to carry out the drying of the array of polymer gel pads on the support of Guschin et al or Khrapko et al or Chetverin et al by freeze drying to obtain the function of freeze drying
25 to produce a porous, highly swellable polymer of a controlled desired

pore size and pore distribution as disclosed by Funk et al. It would have been expected that freeze drying can be used to increase the pore size since Funk et al disclose using the amount of water in the swollen polymer freeze dried to obtain a desired pore size. The further
5 disclosure of Ruchel (1978), Ruchel (1975) or Blank et al of freeze drying a polymer gel to obtain a porous polymer, if needed, would have further suggested carrying out the drying of Guschin et al, Khrapko et al or Chetverin et al by freeze drying. Ruchel (1978), in particular, discloses that freeze drying produces a sponge like structure without gel
10 matrix shrinkage (page 564, lines 15-18).

Response to Arguments

Applicant's arguments filed 11/14/02 have been fully considered but they are not persuasive.

It is granted as urged by applicants that Guschin et al and Khrapko
15 et al do not disclose freeze drying to increase pore size. However, Guschin et al and Khrapko et al disclose drying porous polymer gels, and Chetverin et al discloses lyophilizing (col 12, lines 58-59) which is freezing drying. Since Funk et al disclose freeze drying a polymer gel to obtain a porous polymer gel having a desired controlled pore size and
20 distribution, and the polymer freeze-dried is of the type dried by Guschin et al, Khrapko et al or Chetverin et al, it would have been obvious to freeze-dry the polymer gel of Guschin et al, Khrapko et al or Chetverin et al to obtain the result of a controlled pore size and distribution as suggested by Funk et al.

Applicants assert that Chetverin et al does not disclose an array. However, the present specification (page 5, lines 5-7) states that the technique of U.S. Patent 5,616,478 provide an array of porous polymer pads. In any event, the polymer gel of Chetverin et al is on a solid support and the gel is in a form that can be considered a pad, and it would have been obvious to provide the polymer gel pad of Chetverin et al as an array of porous polymer gel pads when the function of an array is desired since it is conventional and well known in the art to use an array of porous polymer pads for the procedures involving nucleic acid amplification as disclosed by Chetverin et al. Moreover, as compared to other drying methods, freeze-drying would have inherently resulted in a larger pore size since the improvement of the present invention is using freeze-drying in place of known drying techniques.

Contrary to applicants' argument, Funk et al is analogous since Funk et al is directed to freeze-drying a porous polymer gel. One would obviously look to any art dealing with such freeze-drying when desiring to increase pore size of a porous polymer gel irrespective of the intended use of the gel.

Applicants urge that Blank et al and Ruchel (1975) and (1978) do not teach that freeze-drying will increase pore size. However, these references are combined with the Funk et al patent which suggests that freeze-drying can be used to increase pore size.

Applicants urge that there is no motivation to combine Funk et al with Guschin et al, Khrapko et al or Chetverin et al. However, there is clear motivation. The motivation is to obtain in Guschin et al, Khrapko

et al or Chetverin et al the function of freeze-drying when used to dry a polymer gel as disclosed by Funk et al, i.e. to obtain the result of producing a dried polymer gel having a controlled pore size and pore distribution (Funk et al, col 3, lines 15-30). Obviously, controlling pore size and distribution when drying in Guschin et al, Khrapko et al or Chetverin et al would have been expected to an advantage since each reference is drying a porous polymer gel. Furthermore, when freeze-drying the polymer gel of Guschin et al, Khrapko et al or Chetverin et al, a larger pore size will inherently be obtained as compared to using other methods of drying. In the present invention, the pore size increase is with respect to drying methods other than freeze-drying since the improvement as disclosed in the specification is using freeze-drying in place of known drying methods.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

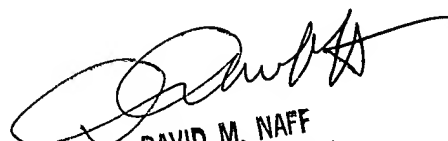
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DMN
2/10/03


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651